Prospective Trial of the Efficacy and Safety of a Personalized Regimen of High-dose Aflibercept 8mg on Treatment-naive Polypoidal Choroidal Vasculopathy: the PALLAS Trial

NCT07389980

Status	RECRUITING
Phase	Phase 3
Sponsor	Yeungnam University College of Medicine
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (4)

- Signed informed consent must be obtained prior to participation in the study.
- Male or female patients e 19 years of age at screening
- Presence of active polypoidal lesions in the macular as shown by ICGA and presence of serosanguinous maculopathy (exudative or hemorrhagic features involving the macula on floor fundus photography, FA and SD-OCT AND presence of IRF or SRF that affects the central subfield as seen by SD-OCT
- Best-corrected visual acuity (BCVA) score between 83 and 23 letters, inclusive, using Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity testing charts at both screening and baseline visit (study eye)

Exclusion (8)

- Ocular conditions/disorders at screening or baseline which could, in the opinion of the investigator, prevent response to study treatment or may confound interpretation of study results, compromise visual acuity or require planned medical or surgical intervention during the first 12-month study period, structural damage of the fovea, atrophy or fibrosis at the center of the fovea (study eye)
- A history of any evidence of type 2 or type 3 neovascularization, myopic choroidal neovascularization, or other ocular disorders
- Total area of subretinal hemorrhage larger than 9DA or comprising e 50% of the lesion area or presence of vitreous hemorrhage in study eye
- Any active intraocular or periocular infection or active intraocular inflammation, at screening or baseline (study eye)
- Uncontrolled glaucoma defined as intraocular pressure (IOP) \> 25 mmHg on medication, or according to investigator's judgment, at screening or baseline (study eye)

... and 3 more (see full listing online)

Locations (1 total)

Yeungnam University Hospital, Daegu, South Korea